

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Office of the Director

2019 TRIENNIAL ADVISORY COUNCIL REPORTS
CERTIFYING COMPLIANCE WITH THE
NIH POLICY ON INCLUSION GUIDELINES

Martha J. Somerman, DDS, PhD
Director, National Institute of Dental and Craniofacial Research

January 2019

NATIONAL ADVISORY DENTAL AND CRANIOFACIAL RESEARCH COUNCIL
REPORT MONITORING ADHERENCE TO THE NIH POLICY ON THE INCLUSION
OF WOMEN AND MINORITIES IN CLINICAL RESEARCH
AS REPORTED IN FY 2016 THROUGH FY 2018
January 23, 2019

BACKGROUND/OVERVIEW

The mission of the National Institute for Dental and Craniofacial Research (NIDCR) is to improve dental, oral, and craniofacial (DOC) health. We accomplish our mission by:

- Performing and supporting basic, translational, and clinical research;
- Conducting and funding research training and career development programs to ensure an adequate number of talented, well-prepared, and diverse investigators;
- Coordinating and assisting relevant research and research-related activities among all sectors of the research community; and,
- Promoting the timely transfer of knowledge gained from research and its implications for health to the public, health professionals, researchers, and policy-makers.

The NIDCR improves the nation's DOC health by supporting research discoveries that advance prevention and treatment options for all Americans. These investments are leading to a deeper understanding of the complex underlying biological, behavioral, and social factors that support DOC health or cause disease, and of the relationship between oral and overall health.

The NIH Revitalization Act of 1993 directed the NIH to establish guidelines for inclusion of women and minorities in NIH-funded clinical research. The 21st Century Cures Act, enacted December 13, 2016, included several new requirements related to inclusion of participants in clinical research. As a result, NIH updated its [Policy on the Inclusion of Women and Minorities in Clinical Research](#) on November 28, 2017, to require studies that are NIH-defined Phase III clinical trials and/or applicable clinical trials to report the results of analyses by sex/gender and/or race/ethnicity to ClinicalTrials.gov. This requirement is effective for competing grant awards on or after December 13, 2017, as well as contract solicitations and Intramural studies initiated after this date. Additionally, NIH revised its Inclusion of Children policy on December 19, 2017. The revised policy, now called the [NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects](#), addresses consideration of individuals of all ages in NIH-funded clinical research and requires reporting of participant age at enrollment in annual progress reports. The policy is effective for applications submitted on or after January 25, 2019, and contract solicitations and Intramural studies initiated after this date.

The 21st Century Cures Act also amended the frequency from biennial to triennial for reporting inclusion activities to advisory councils and providing the Report of the NIH Director on the Inclusion of Women and Minorities. Thus, this first triennial report provides information from each NIH Institute and Center (IC) on inclusion of participants in NIH-defined clinical research from Fiscal Year (FY) 2016 through FY 2018. Section IV of the [Report of the Advisory Committee on Research on Women's Health](#) includes IC reports on monitoring adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research for FY 2015 and 2016. This report presents the NIDCR's activities related to fulfilling its responsibilities under these statutes.

STRATEGIES FOR ENSURING POLICY COMPLIANCE

The implementation of inclusion guidelines involves the participation of NIH Review, Program, and Grants Management staff. As part of the peer review process, each application that involves human subjects must be evaluated for the appropriateness of the proposed plan to adhere to the inclusion requirements, detailed in the [Guidelines for the Review of Inclusion on the Basis of Sex/Gender, Race, Ethnicity and Age in Clinical Research](#), issued in April 2016. For NIH-defined Phase III clinical trials, enrollment goals are further assessed for plans to conduct analyses of intervention effects among sex/gender, racial, and ethnic groups when appropriate. Reviewers on NIH peer review panels make recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. Unacceptable inclusion plans must be reflected in the priority score of the application and documented in the minutes of the review session.

Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received. Prior to funding a new award, Program staff are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. For NIH-defined Phase III clinical trials, Program staff review applications for the requirement that sex/gender and race/ethnicity analyses be planned. Grants Management staff ensure that applications with unacceptable inclusion plans are resolved prior to issuing an award. Further, for awards that require inclusion monitoring, Program staff monitor actual enrollment progress in annual and final progress reports and provide consultation when necessary. For NIH-defined Phase III clinical trials, Program staff monitor annual and final progress reports for the requirement to conduct analyses by sex/gender and race/ethnicity. Grants Management staff ensure that appropriate terms and conditions of award are included in the Notice of Award, and that inclusion information is appropriately documented in the official grant file.

All Intramural clinical research studies require investigators to provide plans for the appropriate inclusion of women and minorities and/or a justification whenever representation is limited or absent, as part of their NIH protocol reviews. Intramural IRBs review research protocols for compliance with inclusion guidelines and conduct annual monitoring. With each annual review and renewal, the Intramural investigator

documents the number, sex/gender, race, and ethnicity of those who were accrued during the past year; any issues with accrual are addressed at the annual review by the investigator and reviewed by the pertinent IRB. Dr. Janice Lee, Clinical Director of the Intramural Program at NIDCR, is responsible for overseeing protocol recruitment efforts of NIDCR Intramural investigators and ensuring they make efforts to include women and minorities in their studies. The Clinical Center's Office of Protocol Services (OPS) coordinates annual reporting of demographic participant data to the Office of Extramural Research (OER) and the Office of Research on Women's Health.

The NIH Revitalization Act of 1993 and subsequent statutes have stipulated that NIH staff and Extramural investigators understand the requirement of the statutes and their impact on the conduct of clinical research. Dr. Jane C. Atkinson, who was Director for the Center for Clinical Research, NIDCR, during FY2016 and FY2017, provided guidance to NIDCR Extramural Program Directors about the requirement. Beginning in FY2018, Dr. Dena Fischer, Acting Director for the Center for Clinical Research, Division of Extramural Research, NIDCR, has transitioned into the role to provide guidance to NIDCR's Extramural Program Directors about the inclusion guidelines. Dr. Fischer is a member of the NIH Inclusion Operating Procedures Workgroup, which reviews the tracking system used by NIH to capture inclusion data and recommends changes as needed. NIDCR Extramural Program Directors provide assistance to investigators to ensure that target and enrollment information for the inclusion of human subjects on the basis of sex/gender, race, and ethnicity are included in grant applications and progress reports. Further, NIDCR Program Directors, Scientific Review Officers, and Grants Management staff attended the May 11, 2018 training, "Ensuring Inclusion in NIH Clinical Research: Policies and Procedures for Grants and Contracts." Staff may access the archived training on the NIH staff intranet.

ANALYSIS AND INTERPRETATION OF DATA

Analysis of the FY 2016 through FY 2018 NIDCR inclusion data shows that substantial numbers of women, and minorities of both sexes/genders, were enrolled in NIDCR-funded clinical research.

All NIDCR Extramural and Intramural Clinical Research Studies

In FY 2016, 65,215 participants were enrolled in 119 of 141 NIDCR-supported Extramural and Intramural studies that required enrollment monitoring. In FY 2017 56,406 participants were enrolled in 129 of 154 NIDCR-supported Extramural and Intramural studies that required enrollment monitoring, and in FY 2018, 68,365 participants were enrolled in 152 of 178 NIDCR-supported clinical studies that required enrollment monitoring.

Aggregate FY 2016 data (Table 2) revealed 54.2% of enrolled participants were female, 43.7% were male, and sex/gender was unknown for 2.1%. Similar patterns were present in the aggregate FY 2017 (Table 3) and FY 2018 (Table 4) data in that 53.3%

(2017) and 51.4% (2018) of participants were female, 45.4% (2017) and 47.0% (2018) were male, and sex/gender was unknown for 1.3% in 2017 and 1.6% in 2018.

In FY 2016 through FY 2018 (Tables 2 through 4), Whites had the highest rates of participation (65.0% in FY 2016, 68.0% in FY 2017, 62.7% in FY 2018). Black / African American participation was 15.6% in FY 2016, 8.8% in FY 2017, and 12.5% in FY 2018. In FY 2016, Asian participation was 9.1%; it was 11.6% in FY 2017 and 10.0% in FY 2018. American Indian / Alaska Native participation was 0.5% in FY 2016, 0.6% in FY 2017, and 1.1% in FY 2018. Race was unknown / not reported or refused identification for 5.4% of participants in FY 2016, 6.1% FY 2017, and 8.4% in FY 2018. Black / African American participation was decreased in FY 2017 compared to FY 2016 and FY 2018. Hispanics represented 12.1% of enrolled participants in FY 2016, 13.7% in FY 2016, and 13.8% in FY 2018. Ethnicity was unknown / not reported for 3.7% in FY 2016, 4.4% in FY 2017, and 5.0% in FY 2018. There was a similar ethnic distribution of participants when comparing data between FY 2016 to FY 2018.

Tables 5 through 7 display the total number of participants enrolled in NIDCR-supported Phase III clinical trials between FY 2016 and FY 2018. In FY 2016, 1634 participants were enrolled in five Phase III clinical trials; 1548 participants were enrolled in four Phase III trials in FY 2017, and 1627 participants were enrolled in five Phase III trials in FY 2018. All NIDCR-supported Phase III clinical trials are required to report the results of analyses by sex/gender and/or race/ethnicity to ClinicalTrials.gov. The majority of participants enrolled in these Phase III trials were female (67.3% in FY 2016, 60.2% in FY 2017, and 62.7% in FY 2018). In FY 2016, 65.1% of Phase III clinical trial participants were White; in FY 2017, white participation in Phase III clinical trials was 64.9%, and it decreased to 51.2% in FY 2018. Black / African Americans represented 22.5% of Phase III clinical trial participants in FY 2016; 18.6% of Phase III trial participants were Black / African American in FY 2017, and in FY 2018, 33.1% of Phase III trial participants were Black / African American. Race was unknown or not reported by 5.4% of Phase III clinical trial participants in FY 2016, 8.3% in FY 2017, and 9.6% in FY 2018. Black / African American participation was higher in Phase III trials than in the aggregate clinical studies in FYs 2016 through 2018. In FY 2016, Hispanic enrollment in Phase III trials was 12.7% in FY 2016, 10.1% in FY 2017, and 14.0% in FY 2018, similar to Hispanic enrollment for all clinical research in the same reporting timeframe. Ethnicity was unknown or not reported by 33.3% of Phase III clinical trial participants in FY 2016, 36.1% in FY 2017, and 37.1% in FY 2018.

FY 2018 enrollment data by sex/gender, ethnicity, and race in various Research, Condition, and Disease Categorization (RCDC) Categories will be available at the following link in mid to late January 2019: <https://report.nih.gov/RISR/>.

Table 1. Total Inclusion Enrollment Reports (IERs) for Research Studies Receiving Funding between FY 2016 and FY 2018

Extramural and Intramural NIH-Defined Clinical Research
NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

	FY 2016		FY 2017		FY 2018	
	Phase III trials*	Other Clinical Studies**	Phase III trials*	Other Clinical Studies**	Phase III trials*	Other Clinical studies**
Domestic site IERs	4	107	3	118	4	141
Foreign site IERs	1	7	1	7	1	6
IERs reporting combination of females, males, and/or unknown sex/gender	5	96	4	97	5	129
Female-only IERs	0	11	0	10	0	10
Male-only IERs	0	7	0	7	0	8
Total IERs with enrollment data	5	114	4	125	5	147
Total IERs without enrollment data	2	20	2	23	0	26
Total IERs	7	134	6	148	5	173

IER = Inclusion Enrollment Report, as reported by grantee institution

* An NIH-Defined Phase III Clinical Trial “usually involves several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with standard or control intervention or comparing two or more existing treatments.”

** Human subjects studies that are not NIH-Defined Phase III Clinical Trial

**Table 2: FY2016 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Clinical Research
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment ***

	Total Enrollment by Race								Total Enrollment by Ethnicity			
	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	191 0.3%	2,904 4.5%	6,359 9.8%	30 0.1%	22,796 35.0%	1,568 2.4%	1,521 2.3%	35,369 54.2%	30,076 46.0%	4,434 6.9%	859 1.3%	35,369 54.2%
Male	138 0.2%	2,835 4.3%	3,747 5.7%	26 0.0%	19,422 29.8%	1,228 1.9%	1,103 1.7%	28,499 43.7%	24,501 37.6%	3,415 5.2%	583 0.9%	28,499 43.7%
Unknown	4 0.0%	178 0.3%	74 0.1%	5 0.0%	147 0.2%	6 0.0%	933 1.4%	1,347 2.1%	379 0.6%	17 0.0%	951 1.5%	1,347 2.1%
Total	333 0.5%	5,917 9.1%	10,180 15.6%	61 0.1%	42,365 65.0%	2,802 4.3%	3,557 5.4%	65,215 100.0%	54,956 84.2%	7,866 12.1%	2,393 3.7%	65,215 100.0%

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 119 of 141 total IERs in FY2016

**Table 3: FY2017 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Clinical Research
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment***

Total Enrollment by Race									Total Enrollment by Ethnicity			
	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	194	3,188	2,948	35	20,492	1,502	1,711	30,070	24,527	4,259	1,284	30,070
	0.4%	5.7%	5.2%	0.1%	36.3%	2.7%	3.0%	53.3%	43.5%	7.6%	2.2%	53.3%
Male	138	3,141	2,008	24	17,662	1,171	1,475	25,619	21,255	3,410	954	25,619
	0.2%	5.6%	3.6%	0.0%	31.3%	2.1%	2.6%	45.4%	37.7%	6.0%	1.7%	45.4%
Unknown	7	186	23	5	223	22	251	717	414	37	266	717
	0.0%	0.3%	0.0%	0.0%	0.4%	0.0%	0.5%	1.3%	0.7%	0.1%	0.5%	1.3%
Total	339	6,515	4,979	64	38,377	2,695	3,437	56,406	46,196	7,706	2,504	56,406
	0.6%	11.6%	8.8%	0.1%	68.0%	4.8%	6.1%	100.0%	81.9%	13.7%	4.4%	100.0%

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 129 of 154 total IERs in FY2017

**Table 4: FY2018 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Clinical Research
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment***

Total Enrollment by Race									Total Enrollment by Ethnicity			
	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	407	3,390	4,741	49	21,666	1,999	2,910	35,162	28,232	5,334	1,596	35,162
	0.6%	4.9%	7.0%	0.1%	31.7%	2.9%	4.3%	51.4%	41.4%	7.7%	2.3%	51.4%
Male	335	3,286	3,755	48	21,011	1,484	2,213	32,132	26,797	4,091	1,244	32,132
	0.5%	4.8%	5.5%	0.1%	30.7%	2.2%	3.2%	47.0%	39.2%	6.0%	1.8%	47.0%
Unknown	2	171	30	0	220	11	637	1071	425	36	610	1071
	0.0%	0.3%	0.0%	0.0%	0.3%	0.0%	0.9%	1.6%	0.6%	0.1%	0.9%	1.6%
Total	744	6,847	8,526	97	42,897	3,494	5,760	68,365	55,454	9,461	3,450	68,365
	1.1%	10.0%	12.5%	0.2%	62.7%	5.1%	8.4%	100.0%	81.2%	13.8%	5.0%	100.0%

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 152 of 178 total IERs in FY2018

**Table 5: FY2016 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Phase III Clinical Trials
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment ***

Total Enrollment by Race									Total Enrollment by Ethnicity			
	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	12	12	286	3	710	37	40	1,100	632	144	324	1,100
	0.7%	0.7%	17.5%	0.2%	43.5%	2.3%	2.4%	67.3%	38.7%	8.8%	19.8%	67.3%
Male	7	6	81	2	353	35	50	534	250	63	221	534
	0.4%	0.4%	5.0%	0.1%	21.6%	2.1%	3.0%	32.7%	15.3%	3.9%	13.5%	32.7%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Total	19	18	367	5	1,063	72	90	1,634	882	207	545	1,634
	1.2%	1.1%	22.5%	0.3%	65.1%	4.4%	5.4%	100.0%	54.0%	12.7%	33.3%	100.0%

* Number of Inclusion Enrollment Records (IERs) with Enrollment Data: 5 of 7 total IERs in FY2016

**Table 6: FY2017 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Phase III Clinical Trials
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment***

Total Enrollment by Race									Total Enrollment by Ethnicity			
	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	6	11	187	0	620	48	60	932	527	75	330	932
	0.4%	0.7%	12.1%	0.0%	40.1%	3.1%	3.9%	60.2%	34.1%	4.8%	21.3%	60.2%
Male	7	6	101	2	384	46	69	615	304	82	229	615
	0.5%	0.4%	6.5%	0.1%	24.8%	2.9%	4.4%	39.7%	19.6%	5.3%	14.8%	39.7%
Unknown	0	0	0	0	0	1	0	1	1	0	0	1
	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%	0.0%	0.1%	0.1%	0.0%	0.0%	0.1%
Total	13	17	288	2	1,004	95	129	1,548	832	157	559	1,548
	0.9%	1.1%	18.6%	0.1%	64.9%	6.1%	8.3%	100.0%	53.8%	10.1%	36.1%	100.0%

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 4 of 6 total IERs in FY2017

**Table 7: FY2018 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Phase III Clinical Trials
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment***

	Total Enrollment by Race								Total Enrollment by Ethnicity			
	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	2	11	364	1	516	48	77	1,019	546	119	354	1,019
	0.1%	0.7%	22.4%	0.1%	31.7%	3.0%	4.7%	62.7%	33.6%	7.3%	21.8%	62.7%
Male	1	7	174	0	318	27	77	604	249	109	246	604
	0.1%	0.4%	10.7%	0.0%	19.5%	1.7%	4.7%	37.1%	15.3%	6.7%	15.1%	37.1%
Unknown	0	0	0	0	0	0	4	4	0	0	4	4
	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.2%	0.2%	0.0%	0.0%	0.2%	0.2%
Total	3	18	538	1	834	75	158	1,627	795	228	604	1,627
	0.2%	1.1%	33.1%	0.1%	51.2%	4.7%	9.6%	100.0%	48.9%	14.0%	37.1%	100.0%

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 5 of 5 total IERs in FY2018

APPENDIX – ADDITIONAL TABLES

Appendix Table A: NIDCR Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY2016 and FY2018*

Fiscal Year	Total IERs	IERs Without Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male-only and Female-only*
2016	141	22	119	111	8	11	7	101
2017	154	25	129	121	8	10	7	112
2018	178	26	152	145	7	10	8	134

*Inclusion Data Records (IERs) excluding male-only and female-only include unknown sex/gender, and combination of unknown and any sex/gender(s).

Appendix Table B1: NIDCR Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity

Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2016	Female	14,223	40.2	35,369	54.2	30,076	85.0	4,434	12.5	859	2.4
2016	Male	10,478	36.8	28,499	43.7	24,501	86.0	3,415	12.0	583	2.0
2016	Unknown	284	21.1	1,347	2.1	379	28.1	17	1.3	951	70.6
2017	Female	11,017	36.6	30,070	53.3	24,527	81.6	4,259	14.2	1,284	4.3
2017	Male	9,070	35.4	25,619	45.4	21,255	83.0	3,410	13.3	954	3.7
2017	Unknown	264	36.8	717	1.3	414	57.7	37	5.2	266	37.1
2018	Female	14,521	41.3	35,162	51.4	28,232	80.3	5,334	15.2	1,596	4.5
2018	Male	11,936	37.1	32,132	47.0	26,797	83.4	4,091	12.7	1,244	3.9
2018	Unknown	244	22.8	1,071	1.6	425	39.7	36	3.4	610	57.0

Appendix Table B2: NIDCR Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity (continued)

Year	Sex Gender	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2016	Female	191	0.5	2,904	8.2	6,359	18.0	30	0.1	22,796	64.5	1,568	4.4	1,521	4.3
2016	Male	138	0.5	2,835	9.9	3,747	13.1	26	0.1	19,422	68.1	1,228	4.3	1,103	3.9
2016	Unknown	4	0.3	178	13.2	74	5.5	5	0.4	147	10.9	6	0.4	933	69.3
2017	Female	194	0.6	3,188	10.6	2,948	9.8	35	0.1	20,492	68.1	1,502	5.0	1,711	5.7
2017	Male	138	0.5	3,141	12.3	2,008	7.8	24	0.1	17,662	68.9	1,171	4.6	1,475	5.8
2017	Unknown	7	1.0	186	25.9	23	3.2	5	0.7	223	31.1	22	3.1	251	35.0
2018	Female	407	1.2	3,390	9.6	4,741	13.5	49	0.1	21,666	61.6	1,999	5.7	2,910	8.3
2018	Male	335	1.0	3,286	10.2	3,755	11.7	48	0.1	21,011	65.4	1,484	4.6	2,213	6.9
2018	Unknown	2	0.2	171	16.0	30	2.8	0	0.0	220	20.5	11	1.0	637	59.5

Appendix Table C1: NIDCR Enrollment for All NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2016	Female	473	43.0	1,100	67.3	632	57.5	144	13.1	324	29.5
2016	Male	188	35.2	534	32.7	250	46.8	63	11.8	221	41.4
2016	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2017	Female	322	34.5	932	60.2	527	56.5	75	8.0	330	35.4
2017	Male	235	38.2	615	39.7	304	49.4	82	13.3	229	37.2
2017	Unknown	1	100.0	1	0.1	1	100.0	0	0.0	0	0.0
2018	Female	527	51.7	1,019	62.6	546	53.6	119	11.7	354	34.7
2018	Male	301	49.8	604	37.1	249	41.2	109	18.0	246	40.7
2018	Unknown	0	0.0	4	0.2	0	0.0	0	0.0	4	100.0

Appendix Table C2: NIDCR Enrollment for All NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity (continued)

Year	Sex Gender	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2016	Female	12	1.1	12	1.1	286	26.0	3	0.3	710	64.5	37	3.4	40	3.6
2016	Male	7	1.3	6	1.1	81	15.2	2	0.4	353	66.1	35	6.6	50	9.4
2016	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2017	Female	6	0.6	11	1.2	187	20.1	0	0.0	620	66.5	48	5.2	60	6.4
2017	Male	7	1.1	6	1.0	101	16.4	2	0.3	384	62.4	46	7.5	69	11.2
2017	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0
2018	Female	2	0.2	11	1.1	364	35.7	1	0.1	516	50.6	48	4.7	77	7.6
2018	Male	1	0.2	7	1.2	174	28.8	0	0.0	318	52.6	27	4.5	77	12.7
2018	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	100.0